



# SHANNON CLINIC

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**Food and Drug Administration**  
**5630 Fishers Ln., Rm. 1061**  
**Rockville, MD 20852**

Dear Sir:

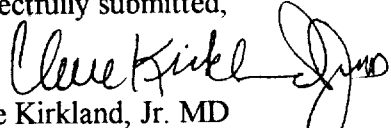
I am writing to express my concerns over proposed changes to the tissue bank rules. Under the Final rules published July 1997, Medical Examiner tissues were exempted from the family/treating physician interview requirements. Due to concerns about CJD, I understand that the new proposed rule will remove this exemption. This will adversely impact the donor cornea supply.

In many of our largest eye banks, up to 60% of the usable tissue comes from the medical examiner. Much of this tissue will be lost due to no available family, or the timeliness in contacting family: i.e. too long a death-to-excision time because of difficulties finding a family member. Much of the tissue distributed through the medical examiner's office is the result of accident, homicide, or suicide in otherwise healthy individuals. There is no medical reason to require an interview to exclude such chronic illnesses as CJD or rabies. I feel the rule changes go too far: the aim of FDA is to protect the public from communicable diseases, but there needs to be a balanced approach or the rule will precipitate a nationwide disruption of the corneal donor pool. Either modify the rule to exempt medical examiner tissue from healthy individuals dying accidentally or through violence, or leave the medical examiner exemption in place.

As a rural corneal transplant surgeon, the availability of tissue from a large medical examiner-based eye bank has a dramatic impact on my ability to help my blind patients restore their vision. A 40-50% drop in the donor pool will dramatically affect transplant waiting lists. Patients in West Texas will become further underserved.

Please reconsider the medical examiner exemption to the Final Rule. Leave it alone, or modify it to reflect interviews for those patients that were ill or hospitalized prior to death.

Respectfully submitted,

  
Cleve Kirkland, Jr. MD  
Corneal Surgeon, Department of Ophthalmology

97D-0318

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